

the group consisting of Parkinson's disease (PD) and/or a related symptom, autism spectrum disorder (ASD) and/or a related symptom, Alzheimer's disease (AD) and/or a related symptom, depression and/or a related symptom, or constipation and/or a related symptom, wherein the method comprises administering to the subject a therapeutically effective amount of at least one aminosterol, or a salt or derivative thereof, provided that the method of administering does not comprise oral administration.

[0022] In a second embodiment, the disclosure encompasses a method of treating, preventing, and/or slowing the onset or progression in a subject in need of a condition selected from the group consisting of schizophrenia and/or a related symptom, erectile dysfunction and/or a related symptom, high blood pressure (HBP) and/or a related condition, low blood pressure (LBP) and/or a related condition, multiple system atrophy and/or a related symptom, Cardiac Conduction Defects and/or a related symptom, wherein the method comprises administering to the subject a therapeutically effective amount of at least one aminosterol, or a salt or derivative thereof. The method of administration can comprise, for example, oral nasal, sublingual, buccal, rectal, vaginal, intravenous, intra-arterial, intradermal, intraperitoneal, intrathecal, intramuscular, epidural, intracerebral, intracerebroventricular, transdermal, or any combination thereof.

[0023] In a third embodiment, the disclosure encompasses a method of treating a subject in need, wherein the subject has a condition amenable to treatment and/or prevention and/or amelioration with an aminosterol, comprising determining a dose of an aminosterol or a salt or derivative thereof for the subject, wherein the aminosterol dose is determined based on the effectiveness of the aminosterol dose in improving or resolving a symptom being evaluated, wherein the symptom is related to the condition, followed by administering the aminosterol dose to the subject for a period of time, wherein the method comprises: (a) identifying a symptom to be evaluated; (b) identifying a starting aminosterol dose for the subject; (c) administering an escalating dose of the aminosterol to the subject over a period of time until an effective dose for the symptom being evaluated is identified, wherein the effective dose is the dose where improvement or resolution of the symptom is observed, and fixing the aminosterol dose at that level for that particular symptom in that particular subject; and (d) optionally wherein each defined period of time is independently selected from the group consisting of about 1 day to about 10 days, about 10 days to about 30 days, about 30 days to about 3 months, about 3 months to about 6 months, about 6 months to about 12 months, and about greater than 12 months.

[0024] In one aspect, the therapeutically effective amount of at least one aminosterol, or a salt or derivative thereof can comprise: about 0.1 to about 20 mg/kg body weight of the subject; and/or about 0.1 to about 15 mg/kg body weight of the subject; and/or about 0.1 to about 10 mg/kg body weight of the subject; and/or about 0.1 to about 5 mg/kg body weight of the subject; and/or about 0.1 to about 2.5 mg/kg body weight of the subject; and/or about 0.001 to about 500 mg/day; and/or about 0.001 to about 250 mg/day; and/or about 0.001 to about 125 mg/day; and/or about 0.001 to about 50 mg/day; and/or about 0.001 to about 25 mg/day; and/or about 0.001 to about 10 mg/day; and/or about 0.001 to about 6 mg/day administered intranasal; and/or about

0.001 to about 4 mg/day administered intranasal; and/or about 0.001 to about 2 mg/day administered intranasal; and/or about 0.001 to about 1 mg/day administered intranasal; and/or about 1 to about 300 mg/day administered orally; and/or about 25 to about 300 mg/day administered orally.

[0025] The present application also relates to compositions and methods for treating and/or preventing a variety of symptoms and disorders related thereto with aminosterols or pharmaceutically acceptable salts or derivatives thereof. Certain embodiments describe the determination and administration of a "fixed dose" that is not age, size, or weight dependent but rather is individually calibrated.

[0026] In one embodiment, the invention encompasses methods of treating a subject in need comprising determining a dose of an aminosterol or a salt or derivative thereof for the subject, wherein the aminosterol dose is determined based on the effectiveness of the aminosterol dose in improving or resolving a symptom being evaluated, followed by administering the aminosterol dose to the subject for a period of time. The method comprises the steps of (a) identifying a symptom to be evaluated; (b) identifying a starting aminosterol dose for the subject; (c) administering an escalating dose of the aminosterol to the subject over a period of time until an effective dose for the symptom being evaluated is identified, wherein the effective dose is the dose where improvement or resolution of the symptom is observed, and fixing the aminosterol dose at that level for that particular symptom in that particular subject.

[0027] In the methods of the invention, the aminosterol or a salt or derivative thereof can be administered via any pharmaceutically acceptable means. For example, the aminosterol or a salt or derivative thereof can be administered orally, intranasally, by injection (IV, IP, or IM) or any combination thereof. The aminosterol or a salt or derivative thereof can be formulated with one or more pharmaceutically acceptable carriers or excipients.

[0028] In one embodiment, starting dosages of the aminosterol or a salt or derivative thereof for oral administration can range, for example, from about 10 mg up to about 150 mg. In another embodiment, the composition is administered orally and the dosage of the aminosterol or a salt or derivative thereof is escalated in about 25 mg increments. In yet another embodiment, the composition is administered orally and the dose of the aminosterol or a salt or derivative thereof for the subject following dose escalation is fixed at a range of from about 25 mg up to about 500 mg.

[0029] In another embodiment, the composition is administered intranasally and the starting aminosterol or a salt or derivative thereof dosage ranges from about 0.001 mg to about 3 mg, or any amount in-between these two values. For example, the starting aminosterol dosage for IN administration, prior to dose escalation, can be, for example, about 0.001, about 0.005, about 0.01, about 0.02, about 0.03, about 0.05, about 0.06, about 0.07, about 0.08, about 0.09, about 0.1, about 0.15, about 0.2, about 0.25, about 0.3, about 0.35, about 0.4, about 0.45, about 0.5, about 0.55, about 0.6, about 0.65, about 0.7, about 0.75, about 0.8, about 0.85, about 0.9, about 1.0, about 1.1, about 1.25, about 1.3, about 1.4, about 1.5, about 1.6, about 1.7, about 1.75, about 1.8, about 1.9, about 2.0, about 2.1, about 2.25, about 2.3, about 2.4, about 2.5, about 2.6, about 2.7, about 2.75, about 2.8, about 2.9, or about 3 mg.

[0030] In another embodiment, the composition is administered intranasally and the dosage of the aminosterol or a